

REMARKS

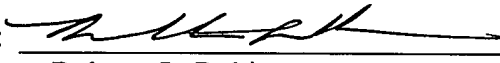
Claims 1-38 have been canceled and new claims 39-80 substituted therefor. Cancellation of these claims is without prejudice and without intent to abandon any originally claimed subject matter. Applicants expressly reserve their right to pursue these claims again in a related application.

New claims 39-80 find support in the original claims filed, as well as throughout the specification at, e.g., page 3, line 30 to page 4, line 28; pages 11-12, bridging paragraph; 35, lines 9-28.

Entry of the foregoing amendments is respectfully requested.

Respectfully submitted,

Date: 11/26/01

By: 
Roberta L. Robins
Registration No. 33,208

ROBINS & PASTERNAK LLP
90 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 325-7812
Fax: (650) 325-7823

Version with markings to show changes made

Claims 1-38 have been canceled.

New claims 39-80 have been added:

--39. (New) A pharmaceutical composition comprising a naturally occurring hydrogel and a pharmacologically-active agent, wherein the composition comprises particles suitable for transdermal or transmucosal delivery to a subject by high velocity powder injection.

40. (New) The pharmaceutical composition of claim 39, wherein mean mass aerodynamic diameter of the particles is from 10 to 100 μm .

41. (New) The pharmaceutical composition of claim 39, wherein envelope density of the particles is from 0.8 to 1.5 g/cm^3 .

42. (New) The pharmaceutical composition of claim 39, wherein the hydrogel is an agarose hydrogel.

43. (New) The pharmaceutical composition of claim 39, wherein the hydrogel is a dextran hydrogel.

44. (New) The pharmaceutical composition of claim 39, wherein the hydrogel is a cellulose hydrogel.

45. (New) The pharmaceutical composition of claim 39, wherein the hydrogel is a chitin hydrogel.

46. (New) The pharmaceutical composition of claim 39, wherein the hydrogel is a starch hydrogel.

47. (New) The pharmaceutical composition of claim 39, wherein the particles demonstrate less than about 50% reduction in mass mean diameter in the particle attrition test.

48. (New) The pharmaceutical composition of claim 39, wherein the particles demonstrate less than about 20% reduction in mass mean diameter in the particle attrition test.

49. (New) A pharmaceutical composition comprising an erodible hydrogel and a pharmacologically-active agent, wherein the composition comprises particles suitable for transdermal or transmucosal delivery to a subject by high velocity powder injection.

50. (New) The pharmaceutical composition of claim 49, wherein mean mass aerodynamic diameter of the particles is from 10 to 100 μm .

51. (New) The pharmaceutical composition of claim 49, wherein envelope density of the particles is from 0.8 to 1.5 g/cm^3 .

52. (New) The pharmaceutical composition of claim 49, wherein the hydrogel is formed from N-vinylpyrrolidone.

53. (New) The pharmaceutical composition of claim 49, wherein the hydrogel comprises a polyvinyl alcohol.

54. (New) The pharmaceutical composition of claim 49, wherein the particles demonstrate less than about 50% reduction in mass mean diameter in the particle attrition test.

55. (New) The pharmaceutical composition of claim 49, wherein the particles demonstrate less than about 20% reduction in mass mean diameter in the particle attrition test.

56. (New) A method for making a powdered pharmaceutical composition, said method comprising:

- (a) providing a mixture of pre-formed hydrogel particles;
- (b) contacting the hydrogel particles with an aqueous composition containing a pharmacologically active agent for a period sufficient to allow the agent to associate with the hydrogel particles and be incorporated therewith; and
- (c) separating the hydrogel particles from the aqueous composition in a drying step to obtain a powdered pharmaceutical composition, wherein said composition comprises said hydrogel particles having the active agent incorporated therewith, and further wherein said composition is suitable for use in a transdermal powder injection device.

57. (New) The method of claim 56, wherein the contacting in step (b) is by suspending the hydrogel particles in the aqueous composition containing a pharmacologically active agent for a period sufficient to cause the particles to swell and incorporate the active agent therein.

58. (New) The method of claim 56, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a dry state.

59. (New) The method of claim 56, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a wet, pre-hydrated state.

60. (New) The method of claim 56, wherein the hydrogel particles comprise agarose, dextran, cellulose, chitin, starch, polyvinylpyrrolidone or polyvinyl alcohol.

61. (New) The method of claim 56, wherein the active agent is present in the powdered pharmaceutical composition in an amount ranging from about 0.1 to 85 wt% of the composition.

62. (New) The method of claim 56, wherein the powdered pharmaceutical composition is formed using a freeze-drying step.

63. (New) The method of claim 56, wherein the powdered pharmaceutical composition is formed using a spray-drying step.

64. (New) A method for making a powdered pharmaceutical composition, said method comprising:

- (a) providing a mixture of pre-formed hydrogel particles,
- (b) contacting the hydrogel particles with an aqueous composition containing a pharmacologically active agent for a period sufficient to allow the agent to associate with the hydrogel particles and be incorporated therewith;
- (c) separating the hydrogel particles from the aqueous composition in at least a partial drying step to obtain primary loaded hydrogel particles having the active agent incorporated therewith;
- (d) contacting the primary loaded hydrogel particles with an aqueous composition containing said pharmacologically active agent for a period sufficient

to allow further agent to associate with the hydrogel particles and be incorporated therewith;

(e) separating the hydrogel particles formed in step (d) from the aqueous composition in at least a partial drying step to obtain secondary loaded hydrogel particles having the active agent incorporated therewith; and

(f) drying the secondary loaded hydrogel particles to obtain a powdered pharmaceutical composition.

65. (New) The method of claim 64, wherein prior to step (f), the secondary loaded hydrogel particles formed in step (e) are contacted at least one further time with an aqueous composition containing said pharmacologically active agent for a period sufficient to allow still further agent to associate with the hydrogel particles and be incorporated therewith.

66. (New) The method of claim 64, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a dry state.

67. (New) The method of claim 64, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a wet, pre-hydrated state.

68. (New) The method of claim 64, wherein the hydrogel particles comprise agarose, dextran, cellulose, chitin, starch, polyvinylpyrrolidone or polyvinyl alcohol.

69. (New) The method of claim 64, wherein the active agent is present in the powdered pharmaceutical composition in an amount ranging from about 0.1 to 85 wt% of the composition.

70. (New) The method of claim 64, wherein the powdered pharmaceutical composition is formed using a freeze-drying step.

71. (New) The method of claim 64, wherein the powdered pharmaceutical composition is formed using a spray-drying step.

72. (New) A method for delivering a pharmacologically active agent to a subject in need thereof, comprising:

(a) preparing a particulate pharmaceutical composition comprising a hydrogel and a the pharmacologically active agent;

(b) accelerating said particulate pharmaceutical composition to a high velocity; and

(c) delivering said accelerated particles into a target skin or mucosal site.

73. (New) The method of claim 72, wherein the hydrogel particles comprise agarose, dextran, cellulose, chitin, starch, polyvinylpyrrolidone or polyvinyl alcohol.

74. (New) The method of claim 72, wherein the active agent is a peptide.

75. (New) The method of claim 72, wherein the active agent is a vaccine.

76. (New) The method of claim 72, wherein the mean mass aerodynamic of the particles is from 10 to 100 μm .

77. (New) The method of claim 72, wherein the envelope density of the particles is from 0.8 to 1.5 g/cm^3 .

78. (New) The method of claim 72, wherein the active agent is present in the powdered pharmaceutical composition in an amount ranging from about 0.1 to 85 wt% of the composition.

79. (New) The method of claim 72, wherein the pharmaceutical composition is formed using a freeze-drying step.

80. (New) The method of claim 72, wherein the pharmaceutical composition is formed using a spray-drying step.--